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No. 89-243

IN THE

Supreme Court of the United States

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF CARBON IMPLANTS INCORPORATED AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICUS CURIAE*

Carbon Implants Inc. ("CII") is a fledgling medical device manufacturer which was formed in May 1989. CII's business presently is not affected by the application of 35 U.S.C. § 271(e)(1) to medical devices. However, CII is concerned with the chilling effect on innovation in the medical device industry if the decision by the Court of

Appeals below is reversed. Therefore, CII submits this brief in support of Respondent Medtronic, Inc.[1] CII has obtained the consent of both parties to the filing of this brief.

CII was formed to provide the public with an improved medical device which is critical to the survival of many people in the world today — the replacement heart valve. The ability of the valve to function without failure is essential. If it fails, the person will die. Because of the critical nature of the heart valve, it is subject to the Food and Drug Administration's ("FDA") most rigorous and lengthy approval process.

In the decision below, the Court of Appeals for the Federal Circuit correctly found that the infringement exemption of 35 U.S.C. § 271(e)(1) applies to medical devices. Specifically, the court found that a medical device being tested for uses related to obtaining FDA approval is exempted from any liability for patent infringement.

CII believes that a contrary result would decrease innovation in the medical device industry because of the consequent detrimental impact on small start-up companies. Start-up companies are often formed to develop improvements to existing technology which, in some cases, is patented. Those start-up companies might never be formed if they are not allowed to avail themselves of the section 271(e)(1) infringement exemption. Since they could not begin the FDA approval process until after any relevant patent expired, they would be unable to market their improvements to the public until years after the patent expired. That delay could be a major disincentive to the formation of new medical device companies. Without those start-up

[1] Subsequent to the formation of CII, Medtronic Inc. provided funds to CII for technology development and acquired a nonvoting minority equity interest in CII.

companies, the medical device industry will lose a major source of innovation.

Similarly, the public would be harmed by the added delay in getting the improved device to the public. Therefore, CII urges this Court to affirm the Court of Appeals' decision below.

STATEMENT

The Nature Of A Mechanical Heart Valve

CII's replacement mechanical heart valve is designed to replace either the aortic valve or the left atrioventricular ("mitral") valve which may become damaged due to old age or certain illnesses. Those valves insure that blood being pumped out of the heart does not flow back into the heart. A person will die almost instantly if the blood reverses its flow into the heart.

The CII heart valve has a unique bileaflet design. Basically, the valve is a thin ring with two hinged louvers which open to allow blood flow out of the heart and close to prevent backflow into the heart. The valve also is designed to minimize any disruption which the valve might cause to the dynamics of the blood flow.

CII's replacement heart valve is classified as a Class III medical device under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 360(c). Class III medical devices are those devices which are "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or . . . presents a potential unreasonable risk of illness or injury." *Id.* In view of their critical nature, it is not surprising that those devices must undergo a rigorous premarket ap-

proval process. *Id.* CII anticipates that the approval process for its heart valve will be long and arduous.

The FDA Approval Process For A Heart Valve Manufacturer

The approval process is basically divided into three parts — preclinical research, clinical investigation and approval by the FDA of a Premarket Approval Application ("PMA"). As discussed below, the preclinical research is necessary to obtain the FDA's approval to conduct the clinical investigation which involves people. The clinical investigation, in turn, is needed to support the PMA. An approved PMA is required before the device can be marketed to the public. *See* D. Kessler, S. Pope and D. Sundwall, *The Federal Regulation of Medical Devices,* 317 New England J. of Med. 357 (1987) (hereinafter Kessler).

The preclinical research involves rigorous in vitro or bench testing of the device in a laboratory and implanting of the device in animals. In the case of CII's heart valve, the *in vitro* testing is designed to evaluate the valve's mechanical operability and reliability before it is implanted in a person. One *in vitro* test will be flow testing. Simulated blood will be circulated through all of the valve sizes (about six) under varying conditions to determine the flow pattern of the blood through each valve size. Assuming no major problems, this procedure normally takes from six months to one year.

A second *in vitro test* will be durability testing. Multiple stations will be set up in a laboratory to cycle the heart valve 600 million times which would be equivalent to fifteen years

of heart beats. Thirty-six[2] valves likely will be tested to assure that the results are reliable. If there are no problems, this procedure should last about one and one-half years. However, if problems are encountered, the period can easily increase to two and one-half years.

Running concurrently with the *in vitro* testing will be the animal testing. The valve is anticipated to be implanted in four sheep to determine its operability in a living body. Two to three years can easily be consumed during this preclinical research.

The data gathered from the preclinical research will be used to support an application to the FDA for an Investigational Device Exemption ("IDE"). The IDE must be obtained before the device can be distributed and implanted in people for the clinical investigation. Kessler, *supra* at 360.

The FDA closely regulates the clinical investigation by virtue of the IDE. The application for the IDE must include, for example: (1) a description of the manufacturing methods for the device; (2) a list of all proposed medical investigators, i.e., the surgeons who will implant the valve and monitor its performance; (3) if the device is to be sold, an explanation of why the sale does not amount to commercialization of the device; and (4) a complete investigational plan. 21 C.F.R. § 812.20. The investigational plan must include, among other things: (1) the duration of the investigation; (2) a written procedure for monitoring the investigation; (3) a copy of the materials used to obtain a patient's informed consent; and (4) a description of the

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[2] There are thirty-six valves because: the CII replacement valve can replace two (2) different valves (the mitral valve and the aortic valve); three (3) sizes are tested for each type of valve; and six (6) replacement valves are tested for each size.

patient population, including the number, age, sex and condition. 21 C.F.R. § 812.25.

Assuming there are no significant problems, the clinical investigation typically lasts two and one-half to three years.

After the clinical investigation is completed, the PMA will be prepared and submitted to the FDA. The FDA has 45 days to advise the applicant whether the application has been accepted and filed for a substantive review. 21 C.F.R. § 814.42. After that, the FDA is required to approve or deny the application within 180 days. 21 C.F.R. § 814.40. However, in practice, the FDA takes an average of a year to approve the PMA. Kessler, *supra* at 359. That period can be substantially extended if the FDA requests additional data from the applicant.

From the above discussion, one can see that the FDA approval process for a Class III medical device, such as an improved heart valve, can easily take from six to seven years.

SUMMARY OF ARGUMENT

Where a patent covers a medical device which must be tested for purposes of obtaining approval by the Food and Drug Administration, that testing should be allowed as either: (1) a noninfringing experimental use; or (2) an activity exempted from infringement under 35 U.S.C. § 271(e)(1).

The experimental use defense allows a person to experiment with a patented invention as long as the experimentation does not deprive the patentee of his lawful rewards. Testing of medical devices for FDA approval purposes falls within the requirements of that defense. The preclinical research step mainly involves laboratory testing of the device

with some testing of the device in animals. Since no sales occur and no people are involved, the preclinical research does not affect the financial rewards the patentee can realize.

The clinical investigation stage of the testing is also a noninfringing experimental use. The investigation is done to collect data to convince the FDA of the safety and efficacy of the device. The FDA's regulations ensure that the clinical investigation is not commercial in nature. For example, the duration and size of the investigation are closely monitored. Therefore, any commercial effect on the patent owner is *de minimis* and should not transform the clinical testing from being an experimental use into a potentially infringing commercial use.

Even if the FDA testing is found not to be an excusable experimental use, CII believes that Congress has obviated the need for medical device manufacturers to rely on that defense to infringement. 35 U.S.C. § 271(e)(1) creates a specific infringement exemption for testing of medical devices for purposes of obtaining FDA approval.

Lilly's assertion that medical devices do not come within the section 271(e)(1) infringement exemption is unfounded in view of the statutory scheme of Congress. Congress enacted 35 U.S.C. §§ 156 and 271(e)(1) concurrently to correct the adverse effect the lengthy FDA regulatory process had on the patent system. The two statutes act in unison. Section 156 enables the patent owner to restore part of the patent term effectively lost during the approval process. Section 271(e)(1) enables the public to conduct FDA testing during the term of any applicable patents so that the public can receive the full benefit of the patent disclosure at the expiration of the patent and so that the patent monopoly is not wrongfully extended. Any doubt

that section 271(e)(1) applies to medical devices is eliminated by the fact that section 156 clearly applies to medical devices.

Congress would not have permitted medical device patentees effectively to obtain one extension of the patent term under section 156 and a second extension due to the period that competitors would consume in getting FDA approval. Under Lilly's view, Congress enlarged the patent grant for medical device patentees without any concomitant benefit to the public. Such a construction of section 271(e)(1) would mean that Congress acted contrary to the grant of the patent power as set forth in the Constitution.

ARGUMENT

I. Testing Of Medical Devices For FDA Approval Purposes Is Noninfringing Experimental Use

A. The Goal Of The Patent System Is To Promote The Progress Of The Useful Arts

The constitutional goal of the patent system is "To promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries." U.S. Const., art. 1, sec. 8, cl. 8; *Graham* v. *John Deere*, 383 U.S. 1, 5 (1966). That grant of federal patent power "reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and the useful Arts'." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 109 S. Ct. 971, 975 (1989). Congress may not ignore the standard expressed in the Constitution and must exercise its power within those limits. *Graham*, 383 U.S. at 6.

Congress chose to carry out the goal of the Constitution by providing "the limited grant of the patent monopoly in return for the full disclosure of the patented invention and its dedication to the public on the expiration of the patent." *Scott Paper Co.* v. *Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945). The limited and temporary grant of the patent monopoly was never designed for the inventor's exclusive profit or advantage; rather, the primary object was the benefit to the public or community at large. *Kendall* v. *Winsor*, 62 U.S. (21 How.) 322, 328 (1859); *see also, Mercoid Corp.* v. *Mid-Continent Inc. Co.*, 320 U.S. 661, 665 (1944) ("The public interest is dominant in the patent system."). Therefore, Congress may not "enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby." *Graham*, 383 U.S. at 6.

B. The Experimental Use Defense To Infringement Furthers The Goal Of The Patent System

The experimental use defense was first enunciated by Justice Story in 1813. He recognized that the legislature, in enacting the patent statute, could never have intended to punish one who constructed an infringing machine for "philosophical purposes" or "for the purpose of ascertaining the sufficiency of the machine to produce its described effects." *Whittemore* v. *Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813)(No. 17600). Less than six months later, Justice Story clarified the experimental use exception in *Sawin* v. *Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813)(No. 12,391), stating that:

> [T]he making of a patented machine to be an offence within the purview of [the infringement clause], must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification.

> *Whittemore* v. *Cutter* [Case No. 17,600]. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.

Id. at 555. The fundamental inquiry of the defense is whether the experimentation will deprive the owner of the lawful rewards of his discovery.

The soundness of Justice Story's analysis is supported by the manner in which Congress designed the patent system. The patent laws require a full and complete disclosure of the invention so that any person skilled in the art may make and use the invention. *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 481 (1974). In exchange for that disclosure, "the Federal Government is willing to pay the high price of seventeen years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art." *Id.* Upon expiration of the patent, the public is enabled to practice it and profit by its use. *Id.* In other words, the *quid pro quo* for the patent grant is the disclosure of the invention in sufficient detail to enable one skilled in the art to practice the invention once the patent expires. *Universal Oil Prods. Co.* v. *Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944). Additionally, the disclosure informs the public of the precise scope of the monopoly asserted. *Id.*

Those functions of the patent disclosure show that experimental use of the invention during the patent term is inherent in the patent system. The public must be allowed to experiment with the invention in order to test the sufficiency of the patent disclosure. Otherwise, inventors could get patents without giving the public a complete disclosure of the invention. Similarly, advances in the art and improvements to the invention would be stimulated best by allowing experimentation during the term of the patent.

If experimentation is allowed, then, of course, companies or persons with a business intent should be allowed to experiment with the disclosure, because they would have the greatest motivation to test the patent. *See* Eisenburg, *Propriety Rights and the Norms of Science in Biotechnology Research*, 97 Yale L.J. 177, 219-20 (1987).

The Court of Appeals for the Federal Circuit recently acknowledged the experimental use defense in *Roche Prods., Inc.* v. *Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). However, the *Roche* court's analysis of the experimental use defense, as a practical matter, virtually eliminates that defense. The *Roche* court improperly focused its analysis on whether the experimenter had any ultimate commercial objective, rather than on the character of the experimental use. The court stated that:

> Unlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter's business is a violation of the rights of the patentee to exclude others from using his patented invention.

733 F.2d at 863.

The court incorrectly focused on the future commercial intent of the experimenter instead of on the effect the experimental use had on the patentee's lawful rewards. The error of that analysis is shown by its effect on the patent system. First, commercial entities, who undoubtedly have some future commercial motivation, would be foreclosed from testing the sufficiency of patent disclosures. Second, advances in technology would be stifled. Anyone with any

future commercial aspirations would not be allowed to experiment with a patented invention to improve it. Third, without the ability to experiment with the invention, businesses would be severely hampered in their ability to design around a patent. *See Yarway Corp.* v. *Eur-Control U.S.A., Inc.*, 775 F.2d 268, 277 (Fed. Cir. 1985) ("[T]he incentive to 'design around' patents is a positive result of the patent system.").

Congress acted quickly in reversing the *Roche* court's overly restrictive application of the experimental use defense by enacting section 271(e)(1). In doing so, Congress eliminated any precedential effect *Roche* may have had with respect to the experimental use defense.

> [I]t simply makes no sense to apply *Roche* as precedent to nondrug products when the case has no precedential value as to the specific products of the *Roche* suit, namely, drugs. We can only conclude that Congress intended the enactment of section 271(e)(1) to set aside the *Roche* interpretation of section 271(a) in all of its ramifications.

Eli Lilly and Co. v. *Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir.), *cert. granted*, 110 S. Ct. 232 (1989) (opinion reprinted in Appendix to the Petition for Certiorari at page 1a).

C. The Experimental Use Defense To Infringement Under Section 271 Is The Counterpart Of The Experimental Use Doctrine Under 35 U.S.C. § 102

35 U.S.C. § 102(b) provides, in part, that a person is barred from getting a patent if "the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). One of the policies underlying the statutory bar of section 102(b) is "discouraging attempts to extend the length of the period of protection by not allowing the inventor to reap the benefits for more than one year prior to the filing of the application." *T.P. Laboratories, Inc.* v. *Professional Positioners, Inc.*, 724 F.2d 965, 968 (Fed. Cir.), *cert. denied*, 469 U.S. 826 (1984). Stated differently, the intent of the on sale bar in section 102(b) "is to preclude attempts by the inventor or his assignee to profit from commercial use of an invention for more than a year before an application for patent is filed." *D.L. Auld Co.* v. *Chroma Graphics Corp.*, 714 F.2d 1144, 1147 (Fed. Cir. 1983).

Although the language of section 102(b) would appear to prohibit any type of "public use" or "on sale" activity, the courts have construed that language as not including "experimental use." In the seminal case establishing the experimental use doctrine, this Court stated, "The use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as [public use]." *City of Elizabeth* v. *American Nicholson Pavement Co.*, 97 U.S. (7 Otto) 126, 134 (1877).

If experimental activity by the patentee does not act to trigger the one year bar to obtaining a patent, it is logical that analogous experimentation by competitors should not be regarded as an enjoinable act of infringement. That is particularly so in cases where the experimentation is intended to prepare a competing product for market after patent expiration.

1. 35 U.S.C.§ 102(b) Is Designed To Prevent An Inventor From Encroaching Upon The Rights Of The Public

Experimental activities in the public arena prior to filing of a patent application are permitted because they are not viewed as an attempt to extract a longer patent term from the public. As this Court explained in *City of Elizabeth:*

> It is sometimes said that an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law; but this cannot be said with justice when the delay is occasioned by a bona fide effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended.

97 U.S. at 137.

The issue of whether there is a statutory bar to seeking a patent is determined by considering the circumstances surrounding the activity and weighing them against the underlying policies of section 102(b). *UMC Elecs. Co.* v. *United States,* 816 F.2d 647, 656 (Fed. Cir. 1987), *cert. denied,* 484 U.S. 1025 (1988). A sale of the invention does not necessarily negate the bar because, "[w]here, as incident to such [experimental use], the product of its operation is disposed of by sale, such profit from its use does not change its character; but where the use is mainly for the purposes of trade and profit, and the experiment is merely incidental to that, the principle, and not the incident, must give character to its use." *Smith & Griggs Mfg. Co.* v. *Sprague,* 123 U.S. 249, 256 (1887). In other words, sales alone do not indicate that the inventor is trying to impair the rights of the public by extracting a longer patent term.

Similarly, aspirations of future profit also do not trigger the section 102(b) bar because "the mere desire to realize a profit sometime in the future in no way negates the inventor's intent to test his product in the present." *Preemption Devices, Inc.* v. *Minnesota Mining & Mfg. Co.,* 559 F. Supp. 1250, 1259 (E.D. Pa. 1983), *aff'd,* 732 F.2d 903 (Fed. Cir. 1984).

Other factors the courts have considered in determining whether the use was experimental include: (1) whether the inventor maintained control over the invention, *Moleculon Research Corp.* v. *CBS, Inc.,* 793 F.2d 1261, 1266 (Fed. Cir. 1986), *cert. denied,* 479 U.S. 1030 (1987); and (2) whether the inventor told purchasers that the use was for experiments, *In re Dybel,* 524 F.2d 1393, 1401 (C.C.P.A. 1975).

2. The Public's Experimental Use Of A Patented Invention Should Be Allowed Just As The Inventor's Experimental Use Is Allowed

The experimental use defense to infringement is also like the experimental use doctrine under section 102(b) in that the defense helps to insure that the patent term is not extended beyond seventeen years. Nonpatentees must often experiment with making a patented invention to see if they can successfully utilize the invention. If experimentation is not allowed until after the patent expires, then the patentee enjoys a *de facto* patent extension during the period of experimentation by the public. The experimental use defense eliminates that extension.

The analysis for determining whether an activity is a noninfringing experimental use should be the same as the analysis for determining if a use is experimental under section 102(b). Both defenses are concerned with whether the activity is primarily experimental in nature or whether

the activity is mainly commercial in nature. Therefore, like the section 102(b) defense, the character of the noninfringing experimental use should not be destroyed merely because: (a) the experimental user has some future commercial aspirations; or (b) there have been sales which are incidental to the experimental use.

D. Medical Device Testing To Obtain FDA Approval Is An Experimental Use Which Does Not Deprive The Patentee Of His Lawful Rewards

1. The Preclinical Research Has No Commercial Effect On The Patentee

As discussed above, the preclinical investigation involves mechanical type testing and implantation of the device in animals. That investigation clearly does not affect the patentee's lawful rewards because: (1) no devices are sold; and (2) the devices are not implanted in people. Those activities simply cannot affect the patentee's commercial market. Therefore, the preclinical activities should be exempt from infringement liability as experimental uses of the invention.

2. The Purpose Of The Clinical Investigation Is To Obtain Scientific Data For Submission To The FDA And It Has A De Minimis Effect On The Patentee

The FDA's close regulation of the clinical investigation insures that the primary purpose of the investigation is to obtain scientific data. As discussed above, the manufacturer must obtain an Investigational Device Exemption ("IDE")

before conducting the clinical investigation. The policy for allowing IDE's is:

> to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the development of useful devices intended for human use and to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

21 U.S.C. § 360j(g)(1). The FDA has described the purpose of clinical investigations as follows:

> Clinical investigations of medical devices are conducted: *to gather information on device performance*, to determine if a new device is equivalent to a preamendments device, or to determine the safety and effectiveness of a device and *generate data* to justify premarket approval.

Food and Drug Administration, FDA Information Sheets, IRBS AND MEDICAL DEVICES (1989)(Emphasis added). Therefore, the clinical investigation is experimental in nature.

The regulations which implement the FDCA insure that the clinical investigational is not for commercial purposes. If the device is to be sold, an explanation must be given why the sales do not constitute commercialization of the device. 21 C.F.R. § 812.20(b)(8). The price for the device cannot be larger than that needed to recover the costs of manufacture, research, development, and handling. 21 C.F.R. § 812.7(b). Those sales are merely incidental to the clinical testing and are specifically considered noncommercial.

The regulations also insure that the manufacturer's clinical investigation will have a minimal impact on the patentee's commercial market. Before the investigation

begins, the manufacturer must submit an investigational plan which informs the FDA of the number of patients in the investigation and the duration of the investigation. 21 C.F.R. § 812.25. That plan cannot be changed without the approval of the FDA. 21 C.F.R. § 812.35. Also, the manufacturer is under a duty not to unduly prolong the investigation. 21 C.F.R. § 812.7.

The *de minimis* effect of the clinical investigation on the patentee's commercial market is illustrated by CII's replacement heart valve. Only 100-200 replacement valves are anticipated to be implanted into people. The annual market for heart valves in the United States is about 30,000-40,000. Therefore, the total number of heart valves that CII plans to implant is only about four-tenths of one percent of the heart valve market for a single year.

The factors which the court examined in *City of Elizabeth*, to determine that the activities were an experimental use which did not trigger a statutory bar also show that the clinical investigation is an experimental activity.

City of Elizabeth involved the experimental use of an invention relating to road paving. The paving was used to construct part of a toll road so that the inventor could test the qualities of the paving. 97 U.S. at 133. In holding that the experimental use doctrine applied, the court considered several factors. First, the court recognized that the nature of street pavement was such that it could only be satisfactorily experimented on if it was applied to a highway or road, which is necessarily public. *Id.* at 134-37. Second, the court noted that if durability was a concern, then the invention might have to be tested for several years to see if it satisfied its intended purpose. *Id.* In that regard, even if no changes were made during that period, the experimental purpose would not be negated. *Id.* A third factor was

whether the inventor maintained control over the invention. *Id.* Finally, the court noted that the public could derive a benefit from the experimental use.

Turning to clinical research of medical devices for FDA approval purposes, those factors are also present. First, as the FDA has recognized, a device, such as a heart valve, must be implanted into a human to determine its safety and effectiveness. Second, the device must remain in the body for an extended period of time to insure that the device will work properly. Medical devices often change and evolve during the course of the clinical investigation showing that the device is still in development even after it is implanted. J. Stein, *Manufacturers of Medical Devices Join the Chorus of Regulatory Critics*, Nat'l J. 1569 (Sept. 20, 1980). Third, the manufacturer is required to monitor the testing closely to ensure compliance with, among other things, the investigational plan and all applicable FDA regulations. 21 C.F.R. § 812.46. Finally, the patient is required to execute an informed consent before the device is tested on the patient. 21 C.F.R. § 50.25(a)(1). Therefore, the patient clearly knows that the use of the device is for experimental purposes. All of these factors point to excusing the clinical investigation as a noninfringing experimental use.

3. The Public Welfare Will Be Advanced By Allowing Testing For FDA Approval Purposes

The public welfare will be greatly advanced by allowing testing for FDA approval purposes during the patent term. Medical device technology is advancing at an ever increasing pace. Those advances will undoubtedly include improvements to a patented device. Without an experimental use defense, an improvement by someone other than the patentee could not be tested for FDA purposes until expiration of the seventeen year patent term. Instead of being

available to the public when the patent expired, the improvement would not be available until several years after the patent expired. Those years would be saved by allowing FDA testing during the patent term.

II. The Court Of Appeals' Construction Of 35 U.S.C. § 271(e)(1) Furthers The Goals Of The Constitution

CII believes that Congress obviated the need for medical device manufacturers to rely on the judicially recognized experimental use defense when it enacted 35 U.S.C. § 271(e)(1). Petitioner Lilly, however, asserts that section 271(e)(1) does not apply to medical devices. Lilly's construction is inconsistent with Congress' actions and the goals of the Constitution.

A. 35 U.S.C. §§ 156 and 271(e)(1) Were Enacted at the Same Time to Address the Problems Created By the Long FDA Approval Process

Congress recognized that the lengthy FDA approval process adversely affected both the patent rights of the inventor and the interests of the public. For the inventor, the approval process had effectively reduced the patentee's time for exclusive commercial exploitation of his invention. *Eli Lilly and Co.* v. *Medtronic, Inc.*, 872 F.2d at 405; Flannery and Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 270 (1985). One study had indicated that the process lasted seven to thirteen years for a pioneer prescription drug. *Id.* at 301. As discussed above, in the case of a heart valve, the approval period would likely be six to seven years. The seventeen year term that Congress had previously decided was needed to promote innovation was being diminished by

the FDA process. This diminution was shown, for example, in the erosion in pharmaceutical innovation. *Id.* at 302.

The lengthy approval process also impaired the public's ability to fully benefit from the patent disclosure at the end of the patent term. Two cases had established that a company could not undertake the FDA regulatory process until *after* any relevant patent had expired. *See Roche*, 733 F.2d 858; *Pfizer, Inc.* v. *International Rectifier Corp.*, 217 U.S.P.Q. 157 (C.D. Cal. 1982). Therefore, the FDA approval process effectively extended the patent term by the time required to gain FDA approval. Contrary to the scheme of the patent system, the public was denied the immediate benefit of the patent disclosure upon the patent's expiration.

Congress sought to correct the adverse effect of the FDA approval process on the patent system by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, which contained sections 271(e)(1) and 156. Section 156[3] enables patentees to restore part of the patent term which was lost due to the lengthy FDA approval process for, among other things, medical devices. 35 U.S.C. § 156.

Section 271(e)(1)[4] resolves the delay in getting the full benefit of the patent disclosure to the public by allowing one to "make use or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." A company is allowed to complete the approval process during the term of the patent so that when the

[3] Section 201 of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("DPC-PTR Act") added section 156 to title 35 of the U.S. Code.

[4] Section 202 of the DPC-PTR Act added 35 U.S.C. § 271(e)(1)-(4).

patent expires that product can be offered to the public immediately.

Therefore, sections 271(e)(1) and 156 act in unison to reverse the detrimental effect the FDA regulatory requirements had on the patent system.

B. The Court Of Appeals Recognized That Section 271(e)(1) Must Apply To Medical Devices In View Of Section 156

The Court of Appeals recognized that sections 271(e)(1) and 156 were both enacted to address the adverse effects of the FDA regulatory requirements. *Eli Lilly*, 872 F.2d at 404-05. The Court of Appeals rejected Lilly's illogical argument that, in effect, asserted that Congress corrected those problems for drugs, but, with respect to medical devices, acted in favor of the patentee to the detriment of the public.

The patent term restoration provisions of section 156 indisputably apply to medical devices. *Id.* at 405. Therefore, if section 271(e)(1) only applies to drugs, as Lilly asserts, then a medical device patentee would not only be able to restore part of his patent term under section 156, he would also gain the effective patent term extension resulting from the FDA approval process. The patent term could effectively extend to twenty-nine years for a medical device (seventeen years for the patent grant plus seven years for the FDA approval process plus a maximum of five years under section 156). That conclusion implies that Congress decided to increase the patent term for medical devices with no concomitant benefit to the public. Such a result would be against the goals of the Constitution discussed above.

The ability of small medical device companies, such as CII, to develop and compete would be severely hampered

under Lilly's construction of section 271(e)(1). A new company would not be able to offer the public an improvement to a life saving invention until long after any relevant patent expired. Not only could this result deprive the public of the benefit of an improvement for an inordinate period, the delay would likely discourage the formation of new companies.

Lilly's construction of section 271(e)(1) would also put small companies at a competitive disadvantage to large companies like Lilly, and to foreign companies. Under Lilly's view, any testing of an improved medical device which might infringe an existing patent would have to be performed in a foreign country. Foreign companies, of course, could easily test their devices in their home country. Large companies with adequate financial resources could also test in a foreign country. However, most small companies would likely be unable to afford the exorbitant expense of transferring all of their operations to a foreign country. Therefore, small companies such as CII would have to wait six to seven years longer than larger companies, such as Lilly, and foreign companies to enter the market.

CII believes that these severe disadvantages to small start-up companies could be devastating. Not only would small companies find it difficult to compete, many small companies like CII might never be formed. The effect would be a decrease in innovation in the medical device industry because small companies have traditionally been a source of innovation in that industry. Office of Technology Assessment, Congress of the United States, *Federal Policies and the Medical Devices Industry* at 9, 17 (1984).

The court below recognized the error in Lilly's argument stating:

> No persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation.

Eli Lilly, 872 F.2d at 406. That court's decision is in accord with this Court's admonition that "It is the duty . . . of the courts in the administration of the patent system to give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of the Congress." *Graham*, 383 U.S. at 688.

CONCLUSION

For the foregoing reasons, the decision by the Court of Appeals for the Federal Circuit should be affirmed.

Respectfully submitted,

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